BK040084

510(k) Summary of Safety and Effectiveness

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Date of Summary:	February 9, 2005
Trade/Proprietary Name of Device:	ALYX Component Collection System
Common/Usual Name of Device:	Automated Centrifugal Blood Cell Separator
Classification Name of Device:	Automated Blood Cell Separator (21 CFR 864.9245)
Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:	The ALYX System for the collection of one unit of Red Blood Cells (RBC) and concurrent plasma is substantially equivalent to the Baxter Amicus Separator, Cobe Trima and Haemonetics MCS+.
Device Description:	The ALYX instrument and disposable apheresis kit constitute a system for centrifugal blood separation. It is intended for use in blood collection establishments for the collection of one unit of RBCs and concurrent plasma. The instrument has pumps, clamps and valves that move donor blood through the single-use, sterile fluid path disposable kit. Blood components are collected with ACD-A anticoagulant and saline is administered intermittently to the donor throughout the procedure.
Intended Use of the Device:	The ALYX apheresis system is intended for use in blood collection establishments to collect and separate whole blood into its components.

Comparison of Technological Characteristics of the Device vs. the Legally Marketed Device:	The function of the ALYX apheresis system is similar to that of other legally marketed devices such as the Baxter Amicus Separator, Cobe Trima and Haemonetics MCS+. The ALYX System utilizes an apheresis kit that incorporates tubing, a donor needle, a centrifuge chamber and blood product containers manufactured from PVC. The instrument consists of embedded software, pumps, a centrifuge chamber, weigh scales, clamps, a visual and audible alarm and a user-interactive touch screen.
Brief Discussion of Nonclinical and Clinical Tests and Their Results Submitted in the Application:	A clinical study was performed to evaluate the ALYX System for the collection of one unit of leukoreduced RBCs and concurrent Plasma for transfusion or further manufacture. The primary efficacy endpoints for leukoreduced RBC products were met. The collected ACD-A/Adsol RBC units met current FDA standards and are suitable for transfusion. The mean level of Factor VIII recovered from Plasma products was greater than 90 percent and met the primary protocol endpoint. The collected plasma product met protocol requirements and is suitable for use if frozen within eight hours from venipuncture.
Conclusion Drawn from the Nonclinical and Clinical Tests that Demonstrate that the Device is Safe, Effective, and Performs As Well As or Better Than the Legally Marketed Device:	The results of this study demonstrated that subject safety was maintained during the single unit of RBCs and concurrent Plasma collection procedures. Subject pre- and post-procedure vital signs and hematological parameters were within clinically acceptable limits. Data from the study demonstrate that the ALYX system successfully achieves collection of one unit of Red Blood Cells and concurrent Plasma from qualified donors. All testing parameters were within normal limits and are in compliance with current regulatory standards.

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9 February 2005

Date